III. 510(k) SUMMARY

MAY - 9 2008

1. SUBMITTER INFORMATION

A. Company Name:	B.A.S.I.C. Dental Implant Systems, Inc.
B. Company Address:	3321 Columbia NE Albuquerque, NM 87107 USA
C. Company Phone:	(505) 881-1376
D. Company Facsimile:	(505) 884-1923
E. Company Contact: Vice President	Dan Blacklock

2. DEVICE IDENTIFICATION

A. Device Trade Name:	B.A.S.I.C. Dental Implant System
B. Device Common Name:	Dental implant
C. Classification Name:	Endosseous Dental Implant, root-form
D. Device Class:	Class II
E. Device Code:	DZE

3. MODIFIED FROM DEVICE

Trade Name:	BASIC Dental Implant System
510(k) Number:	K013682

III. 510(k) SUMMARY (continued)

4. DEVICE DESCRIPTION & SUMMARY OF DEVICE MODIFICATIONS

The B.A.S.I.C. Dental Implant is an endosseous dental implant.

The implant, healing cap and healing screws will now be provided in a sterilized medical grade Tyvek® pouches in accordance with ISO 11137 (SAL 10^{-6}).

In addition, implants are now provided in diameter of 6.0 mm and lengths of 8.0 mm and 9.0 mm to provide a wider range of options for the dental professional. Per Section 6 of *FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments"*, Dated May 12, 2004, BASIC has conducted a risk analysis which includes health risks related to root form endosseous dental implants. An FMEA report is included in Attachment 9. Furthermore, there are many other cleared root form endosseous dental implants on the market with similar dimensions (Refer to Section 7 of this summary).

There have been no further modifications to the dental implant system.

Per FDA-CDRH criteria for a Special 510(k), the modifications do not affect the intended use or alter the fundamental scientific technology of the device and the modifications to the device fall within the design controls of the device.

5. INTENDED USE

The intended use is identical to the predicate device. For reference the intended use is listed below.

The implant for dental purposes, used to replace missing dental organs (teeth). The Implant is self-tapping (threads) and is screwed into a pilot bore formed in the jawbone. Upon healing, the Implant receives a post, which has a stem, and is adapted to carry dental suprastructures (false teeth).

6. COMPARISON TO PREDICATE DEVICE (UN-MODIFIED DEVICE)

The B.A.S.I.C. Dental Implant is substantially equivalent in the following ways to the identified predicate device;

- Identical technological characteristics
- Identical Indications For Use

III. 510(k) SUMMARY (continued)

6. COMPARISON TO PREDICATE DEVICE (UN-MODIFIED DEVICE), continued

The table below summarizes primary characteristics of the original B.A.S.I.C. Dental Implant and the modified device:

Device Name	B.A.S.I.C. Dental Implant	B.A.S.I.C. Dental Implant -Device Modification	Equivalence Comparison (SE= Substantial Equivalent)
510(k) Number	K013682	Pending	N/A
Implant Diameter	3.5 mm, 4.0 mm and 4.5 mm	3.5 mm, 4.0 mm, 4.5 mm and 6.0 mm	SE[1]: Change in dimensional specification, implant diameter
Implant Length	11 mm, 13 mm and 15 mm	8 mm, 9 mm, 11mm, 13 mm and 15 mm	SE[1]: Change in dimensional specification, implant length
Sterilized Components	All components provided non-sterilized.	Implant, healing cap and healing screws are provided sterilized.	SE[2]: Implantable components are provided sterilized in accordance with ISO 11137 (SAL 10^{-6}) for ease of use.
Material of Implants	CP Titanium.	CP Titanium	SE
Packaging of Implant	Implantable components provided in a non-sterile package with instructions to autoclave for sterilization.	Implantable components provided in sterilized medical grade Tyvek® pouches.	Product improvement

[1] The modification to the dimension and length of the implant does not change the intended use or the fundamental scientific technology of the system. The modification allows for a wider range of options of the dental professional. Diagrams of the implants are provided in Attachments 4-8.

[2] The modification to provide the implantable components sterilized does not change the intended use or the fundamental scientific technology of the system. The modification enables dental professionals without easy access to an autoclave to be able to use the implant in a safe and effective manner.

III. 510(k) SUMMARY (continued)

7. COMPARISON TO OTHER PREDICATE DEVICES

For reference BASIC is including a summary of other predicate devices with cleared implants of similar dimensions, which demonstrate the changes to the dimensional specifications for the implants pose no new health risks to patients.

Device Name	510(k) Number	Device Description	Equivalence Comparison
B.A.S.I.C. Dental Implant -Device Modification	Pending	Implants offered in diameter sizes of 3.5 mm, 4.0 mm, 4.5 mm and 6.0 mm. Implants offered in lengths of 8 mm, 9 mm, 11mm, 13 mm and 15 mm	
3i Osseotite	K063341	Implants are offered in diameter sizes 3.25 mm, 3.75 mm, 4.0 mm, 5.0 mm and 6.0 mm and in varying lengths from 7 mm to 20 mm.	SE
Implant Innovations	K051189	Implants are offered in diameter sizes 3.25 mm to 6.0 mm and with lengths from 8.5 mm to 15 mm.	SE
Bicon	K972417	Implants are offered in 6.0 mm diameter x 8.0 mm length	SE

8. STERILIZATION AND BIOCOMPATIBILITY

B.A.S.I.C. Dental Implant Systems, Inc. has contracted with Steris Isomedix Service to establish and maintain a valid gamma-ray sterilization processes in accordance with ISO 11137 (SAL 10^{-6}) for its B.A.S.I.C. Dental Implant System. Substantiation of a routine sterilization dose was established using the $VDmax^{25}$ method, described in ISO 11137.
Device integrity and functionality were qualified and/or validated using samples produced under routine manufacturing conditions. The B.A.S.I.C. Dental Implant System meets B.A.S.I.C.'s in-house requirements, and requirements listed in ISO 11137, Gamma sterilization for the implantable components, which are now provided in sterilized medical grade Tyvek® pouches.

9. CONCLUSION

The B.A.S.I.C. Dental Implant System is substantially equivalent to the original non-modified device. The previously cleared dental implant design and the proposed dental implant design serve the same intended purpose, are made of the same materials, use the same techniques, and are restored by the dentist using the same methods. The gamma sterilization method used for implantable components is an improvement to the Basic Dental Implant System since the implantable components were not supplied sterilized before. The dimensional specification changes do not pose any new health risks to the patient as there other cleared products on the market with similar dimensions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

B.A.S.I.C. Dental Implant Systems, Incorporated
C/O Mr. Rich Weiskopf
Director Quality Assurance
Reglera LLC
555 Zang Street, Suite 100
Lakewood, Colorado 80228

Re: K072595
Trade/Device Name: B.A.S.I.C. Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 7, 2008
Received: April 10, 2008

Dear Mr. Weiskopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072595

Device Name: B.A.S.I.C. Dental Implant System

Indications for Use:

The implant for dental purposes, used to replace missing dental organs (teeth). The implant is self-tapping (threads) and is screwed into a pilot bore formed in the jawbone. Upon healing, the implant receives a post, which has a stem, and is adapted to carry dental suprastructures (false teeth).

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Hurley for MJR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072595